Important changes regarding butalbital containing products, Kentucky's "exempt" controlled substances and anabolic steroids

Effective September 17, 2014, changes to 902 KAR 55:045 and 902 KAR 55:090 were finalized and adopted. The new regulations may be accessed on the Kentucky Legislative Research Commission website at http://www.lrc.ky.gov/kar/902/055/045.htm and http://www.lrc.ky.gov/kar/902/055/090.htm.

902 KAR 55:045 was adapted to mirror the exempt prescription product list published in Title 21 Code of Federal Regulations §1308.32 with the exception of butalbital containing products. The Federal Exempt Prescription Products List can be located at:

http://www.deadiversion.usdoj.gov/schedules/exempt/exempt_rx_list.pdf#search=Exempted prescription products

ALL BUTALBITAL CONTAINING PRODUCTS (Fioricet, Bupap, Esgic, etc.) are SCHEDULE III CONTROLLED SUBSTANCES in the Commonwealth of Kentucky and are <u>NOT</u> exempt from the licensing, distribution, and recordkeeping provisions of KRS 218A.150-218A.172, 218A.180, and 218A.200. Prescriptions for butalbital containing products <u>must be reported to KASPER</u>.

Effective September 17, 2014, a prescriber without a DEA license cannot write or issue a prescription for a butalbital containing product. In addition, any remaining refills on a butalbital containing product prescription issued by a prescriber <u>without</u> a valid DEA license may <u>NOT</u> be dispensed.

If a DEA licensed prescriber issued a prescription for a butalbital containing product with refills <u>AND</u> it has not been more than 6 months from the date written, it <u>MAY</u> be refilled. Exception: APRNs who have a valid DEA Number are not permitted to write refills for butalbital containing products as APRNs are not permitted to write refills on Schedule III medications.

What does this mean to prescribers?

- All butalbital containing products are schedule III controlled substances.
- A valid DEA Number is required to prescribe butalbital containing products.
- Written prescriptions for a butalbital containing product must be written on a controlled substance prescription blank.
- Follow your licensing board guidelines regarding when to query KASPER prior to prescribing a Schedule III medication.
- Prescriptions for butalbital containing products may have up to 5 refills and are only good for 6 months from date of issuance.
- Prescriptions for butalbital containing products may not be pre-signed or post-dated.

What does this mean to pharmacies?

- Pharmacies that did not conduct an inventory of butalbital containing products prior to October 17, 2014 must conduct an inventory of ALL butalbital containing products **IMMEDIATELY**.
- Pharmacies will now include butalbital containing products in their biennial controlled substance inventory.
- Prescriptions for butalbital containing products will be submitted to KASPER in accordance with 902 KAR 55:110.
- Prescriptions submitted to KASPER for a butalbital containing product will not be successfully
 uploaded if the provider does not have a DEA Number. Please ensure that your computer
 system reflects the correct data for the prescriber.

902 KAR 55:090 was adapted to mirror the exempt anabolic steroid list published in Title 21 Code of Federal Regulations §1308.34. This Federal Anabolic Steroid list can be found at: http://www.deadiversion.usdoj.gov/schedules/exempt/exempt anabolic list.pdf.

For questions regarding the changes made to 902 KAR 55:045 and 902 KAR 55:090, please call the Drug Enforcement and Professional Practices Branch at 502-564-7985.